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Strategic Alignment and Resource Planning Checklist 3.4

STUDY IDENTIFICATION

Branch / Lab: _____ PI: _____

Study Title: _____

POTENTIAL SIGNIFICANCE OF THE STUDY

1. Why might this study have important consequences for the field?

2. How would leaders in this field consider this study to be of high impact? (check all that apply)

- ☐ Success likely to lead to a significant change in paradigm in treatment and/or research
  (Indicate how it may change the paradigm)
- ☐ Study would rarely be done elsewhere and/or could not be easily done on the outside
  (Indicate why this study should be done at the CCR)
- ☐ Incorporating new and/or novel approaches
  (Indicate what new/novel approaches will be utilized and if these approaches originated at the NIH/NCI)
- ☐ Other

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3. What is the roadmap going forward after completing the study? (**complete both 3a & 3b**)

3a. If the study yields positive results:

3b. If the study yields negative results:

4. Is this a direct translation of CCR laboratory research and/or an extension of a prior clinical trial at CCR? ◯ Yes ◯ No

If **YES**, explain how this study fits within the existing program:

If **NO**, explain why the new clinical area is important to be conducted at the CCR:

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Operational Feasibility

5. Is this a study of a rare cancer and/or under-studied population? ◯ Yes ◯ No

If **YES**, briefly describe this population:

If **NO**, how prevalent is the clinical condition to be studied and how widely dispersed are the patients to be recruited (across the United States and at CCR).

6. Is this a CCR investigator-initiated clinical study? ◯ Yes ◯ No

7. Does the study use investigational drug(s) / device(s)? ◯ Yes ◯ No

If YES, please identify where the drugs/devices were developed (check all that apply)

☐ CCR ☐ Industry

☐ CTEP ☐ Other: _____

Who currently holds the IND(s) / IDE(s)?

8. Is the study a multi-institutional study? ◯ Yes ◯ No

If **YES**, is the CCR the Lead Coordinating site of the study? ◯ Yes ◯ No

9. Is the study collaborative with other clinical research branches at the NIH/NCI? ◯ Yes ◯ No

If **YES**, specify specific collaborations

10. Is the study collaborative with others outside the NIH / NCI? ◯ Yes ◯ No

If **YES**, please identify:

11a. How many secondary objectives/endpoints does the study have?

11b. Do any of the secondary objectives/endpoints require invasive procedures? ◯ Yes ◯ No

11c. If YES, is the trial appropriately powered to sufficiently validate secondary objectives / endpoints requiring invasive procedures? ◯ Yes ◯ No

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STUDY UTILIZATION OF UNIQUE NIH RESOURCES

12. Does this study or its correlatives take advantage of the unique resources that exist at the NIH? ◯ Yes ◯ No

If **YES**, please check all that apply:

- ☐ Requires the use of resources not usually reimbursable at other institutions
- ☐ Intensive and/or comprehensive internal pharmacokinetic studies
- ☐ Intensive and/or comprehensive internal pharmacodynamic studies
- ☐ Use of existing or building of a new longitudinal tissue bank
- ☐ Manufacturing of investigational therapy requiring CCR / NIH resources (i.e. cell based treatments, generation of vaccines)
- ☐ Access to resource- intensive imaging studies
  - ☐ Clinical Center Imaging
  - ☐ Molecular Imaging Program
- ☐ Genomics, molecular profiling
  - ☐ Laboratory of Pathology
  - ☐ Clinomics
  - ☐ Clinical Molecular Profiling Core
- ☐ Unique & adaptive study design/methodologies
- ☐ Other

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RESOURCE UTILIZATION

13. Identify specifically who will support the study :
(*Contact ORN)*

Identify the specific names of the **research nurse(s)** who will be assigned to the study

Identify the specific names of the **NP(s) and/or staff clinician(s)** who will be assigned to the study

14. The following resources are being requested from CCR to support this study:
(Check all that apply)

◯Yes ◯No	Personnel (e.g. research nurses, data managers, physician extender) What specific responsibilities & gaps will the additional personnel fill?
◯Yes ◯No	Clinical Trial Support Supplies & Services (e.g. assays) List the type of S&S and specific costs requested
◯Yes ◯No	Pharmaceutical Agents / Devices List specific agent and estimated amount requested
◯Yes ◯No	Monitoring of the study when IND is held by the CCR List specific monitoring requirements and estimated level of support
◯Yes ◯No	Monitoring of the multi-institutional study when the CCR is the coordinating site (except CTEP sponsored protocols) List specific monitoring requirements and estimated level of support
◯Yes ◯No	Patient Recruitment List specific patient recruitment activities and requested level of support
◯Yes ◯No	Other List specific resource requirements and estimated level of support

15. Will you be using the **Laboratory of Pathology** for any testing beyond standard confirmation of diagnosis utilizing H&E stains?

◯Yes ◯No
[If YES, complete the Laboratory of Pathology Worksheet]

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16. Are there any external funding / resources that will be **requested from external sources**? If Please identify who is or may be providing funding/resources and identify the current status (signed agreement, currently in progress, not initiated). If no, type in "N/A".

16a. Pharmaceutical Agents/ Devices (list all involved)

16b. IND monitoring

16c. Monitoring of multi-institutional studies

16d. Support for secondary endpoints

17. Briefly describe any additional potential outside source(s) of funding / resources that may be requested:

Any potential outside source(s) of funding/resources that do not come through will require the resubmission of the concept and SARP Form

Please add any additional comments regarding the strategic importance and/or resource requirements for this study:

Principal Investigator Signature Date

Branch Chief Signature attests the following:

- The information presented on the SARP form is accurate
- The Branch has determined that the study fits within the mission of the branch.
- The Branch has determined that the study design is feasible
- The Branch has reviewed the resources
- The PI has discussed the concept and resource requirements with the study team (PSO, Nursing, NP/PA)

Branch Chief Signature Date

PI Response | SRC Response | Sign-off Form | Reset Form | Save as...

Protocol Pathology Worksheet

Complete if you selected "Laboratory of Pathology" on Question 12 and/or Question 15

STUDY INFORMATION

Branch / Lab: _____ PI: _____

Study Title: _____

Designated Pathologist and/or Associate investigator: _____

Anticipated Enrollment:
Adults _____ Pediatric _____ Both _____

PATHOLOGY RELATED PROTOCOL REQUIREMENTS

1. Does the study require any pathology related protocol **pre-entry** requirements? ○ Yes ○ No

If **YES**, please identify specific requirements

- ☐ Required tumor type(s) **Note 1**
  Specify: _____
- ☐ Other required pathology **Note 2**
  Specify: _____
- ☐ Required biomarkers **Note 3**
  Specify: _____
- ☐ Required Genetics **Note 4**
  Specify: _____
- ☐ Other
  Specify: _____

2. Does the study require any pathology related protocol **post-entry** requirements? ○ Yes ○ No

If **YES**, please identify specific requirements **Note 5**

- ☐ Anticipated surgical procedures / biopsies
  Specify: _____
- ☐ Anticipated fine needle aspiration biopsies
  Specify: _____
- ☐ Anticipated body fluid or cell preparation evaluations
  Specify: _____
- ☐ Anticipated blood or bone marrow evaluation (flow, molecular, cytogenetics)
  Specify: _____
- ☐ Anticipated autopsy evaluations
  Specify: _____
- ☐ Biomarker evaluation **Note 6**
  Specify: _____
- ☐ Tissue procurement **Note 7**
  Specify: _____
- ☐ Other
  Specify: _____

3. Summary of Pathology Service Requirements: **Note 8**

	Estimated # of Patients	Notes (including routines/patient requirements)
Required Flow Cytometry		
Required Cytogenetics (G bands)		
Required Cytogenetics (FISH)		
Required Molecular Testing Specify: _____		
Required FISH (on paraffin tissue sections)		
Routine Light Microscopy		
Cytopathology – FNA services		
Cytopathology – Other fluids or cell preparations		
Required IHC Tests Specify: _____		
Required EM Examination		
Other Requirements Specify: _____		

4. Please add any additional comments regarding pathology resource requirements for this study